## Remarks

Claims 27-29 and 52-59 are pending in this application. No claim amendments are made in this paper.

A. The Rejection Under 35 U.S.C. § 102 Should Be Withdrawn

On pages 2-3 of the Office Action, the rejection of claims 27-29 and 52-59 under 35 U.S.C. § 102 is maintained as allegedly anticipated by Taft *et al.*, *Drug Metabolism and Disposition* 25(10): 1215-1218 (1997) ("Taft"). In response to Applicants arguments previously submitted in the Response to Office Action dated January 2, 2003, the Examiner expresses his disagreement to Applicants' assertion that "Taft does not describe the administration of a venlafaxine derivative such as O-Desmethylvenlafaxine ("ODV") to humans." Specifically, the Examiner alleged that Taft, by disclosing ODV is an antidepressant and a major metabolite of venlafaxine, teaches that "one would administer ODV inherently when giving the parent drug venlafaxine." Applicants respectfully disagree.

Applicants again respectfully invite the Examiner's attention to the standards governing the rejections based on anticipation. As the Examiner is aware, a prior art reference must disclose all the elements of a claim in order to anticipate the invention recited by that claim. *Manual of Patent Examining Procedure* (MPEP) § 2131. There must be no difference between the claimed invention and the reference disclosure as viewed by one of ordinary skill in the art. *Scripps Clinic & Research Fdn. v. Genentech*, 927 F.2d 1565, 1576 (Fed. Cir. 1991). Put another way, "[a] claim is anticipated and therefore invalid only when a single prior art reference discloses each and every limitation of the claim." *Glaxo Inc. v. Novapharm Ltd.*, 52 F.3d 1043, 1047, cert. denied, 116 S. Ct. 516 (1995) (citations omitted) (emphasis added).

In the event a reference does not explicitly teach all elements of a claim, anticipation can only be shown by inherency if, and only if, the cited reference makes it clear that the missing descriptive matter is necessarily present in the thing described in the reference and that it would be so recognized by one of ordinary skill in the art. *In re Robertson*, 169 F.3d 743, 49 U.S.P.Q.2d 1949 (Fed. Cir. 1999) (citing *Continental Can Company USA Inc. v. Monsanto Company*, 948 F.2d 1264 (Fed. Cir. 1991)). Consequently, inherency cannot be established by probabilities or possibilities: "[t]he mere fact that a certain thing may result from a given set of circumstances is not sufficient to support an assertion of inherency." *In re Oelrich*,

212 U.S.P.Q. 323, 326 (C.C.P.A. 1981) (quoting *Hansgirg v. Kemmer*, 102 F.2d 212, 414 (C.C.P.A. 1939)). Therefore "[i]n relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." MPEP § 2112, citing *Ex parte Levy*, 17 U.S.P.Q.2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in the original).

The claims pending in this application recite methods of treating an affective disorder comprising administering a venlafaxine metabolite to a patient. The claims use the term "administering" in a manner entirely consistent with its conventional meaning, *e.g.*, "to apply as a remedy." *The American Heritage College Dictionary*, 17 (3rd ed., 1997). In other words, a compound that exists outside of the patient is given, or applied, to the patient. The Examiner's assertion that the *in vivo* conversion of venlafaxine into its metabolites constitutes "administration" is entirely contrary to the term's well understood meaning. The assertion is also contrary to the way in which the term is used in the specification of this application. For example, the specification describes dosage forms (*e.g.* , tablets and capsules) of venlafaxine metabolites that can be used in methods of the invention. *See*, *e.g.*, specification, pages 14-18. The disclosure of dosage forms presupposes the existence of a venlafaxine metabolite prior to its administration to a patient.

In sum, Taft does not disclose the administration of a venlafaxine metabolite to a patient, much less the administration of a venlafaxine metabolite to a patient in an amount sufficient to treat a disease. For the reason, Applicants respectfully request that the rejection of the claims 27-29 and 52-29 under § 102 be withdrawn.

B. The Rejection Under 35 U.S.C. § 103 Should Be Withdrawn

On pages 2-3 of the Office Action, the rejection of claims 27-29 and 52-29 is maintained as allegedly obvious over Taft. Again, the Examiner disagrees with Applicants' previous arguments that administration of ODV is not inherently the same as the administration of venlafaxine. Applicants respectfully maintain that all of the elements of the present invention are not met by the disclosure of Taft for the following additional reasons.

In a previous Office Action dated July 2, 2002, the Examiner alleged that "there is no distinction in administering ODV directly or through the parent drug venlafaxine alone," and thus the limitation of the pending claims directed to the administration of ODV is inherent in Taft. As Applicants pointed out in the previous response, this assertion is completely unsupported.

For the administration of venlafaxine and ODV to be the same, it must be established that: 1) venlafaxine itself is completely inactive, and the antidepressant activity observed when venlafaxine is administered comes wholly from ODV alone; 2) when administered, 100% of the venlafaxine converts to ODV, and the antidepressant activity observed comes from ODV alone; or 3) when administered, a portion of venlafaxine converts into ODV, but not into other metabolites, and the observed antidepressant activity comes from both the venlafaxine and ODV, and venlafaxine and ODV have the identical pharmacological activity. Applicants point out that none of the above is the case.

Taft, by disclosing that venlafaxine and ODV have comparable antidepressant activity, indicates that venlafaxine itself is active. Further, Taft discloses that only about 55% of the venlafaxine converts into ODV and the rest of the venlafaxine converts into other metabolites, and thus ruling out the second and third possibilities. Therefore, Applicants respectfully submit that, inasmuch as the Examiner's assertion of inherency is based on the factually and scientifically unfounded proposition, the rejection of the claims under 35 U.S.C. § 103 should be withdrawn.[1]

## Conclusion

For the foregoing reasons, Applicants respectfully submit that claims 27-29 and 52-59 are allowable, and request that their rejections be withdrawn.

[1] Should the Examiner disagree, Applicants respectfully request that he set forth his factual assertions in an affidavit under 37 C.F.R. 1.104(d)(2). *See* MPEP § 2144.03.

No fee is believed due for this submission. However, should any fees be due for this submission or to avoid abandonment of the application, please charge such fees to Pennie & Edmonds LLP Deposit Account No. 16-1150.

Respectfully submitted,

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